

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  12D0673176	<b>(X3) Date Survey Completed</b>  07/27/2023
<b>Name of Provider or Supplier</b>  Eureka Springs Hospital	<b>Street Address, City, State</b>  24 Norris Street, Eureka Springs, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Through observation, review of the hospital's IQCP for prothrombin time (PT) and activated partial thromboplastin time (PTT) performed on the Accriva Hemochron coagulation analyzer, review of external QC results for PT and PTT testing, lack of documentation, and interview it was determined that the laboratory did not document the performance of external quality control (QC) as required in the IQCP. Findings follow: A) During a tour of the laboratory on 7/26/23 at 9:15 a.m. PT reagent lot # A3CPT 001 and PTT reagent lot # M2JCC 019 were observed in the laboratory reagent refrigerator. B) Review of the laboratory's IQCP for PT and PTT testing on the Accriva Hemochron coagulation analyzer revealed that "external QC will be performed for each new lot and/or shipment of reagents and with each new operator and every 30 days". C) Review of the external QC log for PT and PTT testing revealed that no documentation of external QC results were identified for lot # A3CPT 001 and lot # M2JCC 019. D) In an interview on 7/26/23 at 9:40 a.m., laboratory staff member ( # 8 on the CMS 209 form) confirmed that the lots A3CPT 001 and M2JCC 019 were the lots currently in use for PT and PTT testing and documentation of the date the reagents were put into use and documentation of external QC identified for those lot #'s of reagents was not present.</p>

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

. Through observations made during a tour of the laboratory, review of the FDA Access Data website, lack of documentation, and interviews with staff, it was determined the laboratory failed to document semi-annual test comparison for testing performed on the Beckman Coulter AU480 Chemistry Analyzer and the I-Stat Analyzer. Findings follow: A) During an initial tour of the laboratory at 1:15 p.m. on 7/25/2023, the surveyor observed a Beckman Coulter AU480 Chemistry analyzer and an I-Stat analyzer in the Chemistry section of the laboratory. B) In an interview on 7/27/2023 at 10:03 a.m., the laboratory staff members (#2 and #3 on the CMS-209) stated that the I-Stat serves as a secondary analyzer to the Beckman Coulter AU 480 analyzer for the analytes on the Chem 8+ I-Stat cartridge ( sodium, potassium, chloride, calcium, glucose, blood urea nitrogen, total carbon dioxide and creatinine). C) Review of the FDA Access Data website revealed that the I-Stat Chem 8 + cartridge is categorized as "moderately complex". D.) The surveyor requested documentation of semi-annual comparison of tests performed on both the Beckman Coulter Au480 and the I-Stat Chem 8+ cartridge . None was provided. E) In an interview at 11:03 a.m. on 7/27/2023 the laboratory staff member ( #2 as listed form CMS-209) stated the semi-annual comparison of the Beckman Coulter AU480 and I-Stat analyzer, for those analytes performed in common, was not performed by the Laboratory.